

Notice of Allowability

Application No.

10/743,813

Applicant(s)

RAMESH ET AL.

Examiner

Richard Schnizer, Ph. D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/8/07.
2. ☒ The allowed claim(s) is/are 72,74,75,78-85,96,98,99,102,103,114 and 115.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached.
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>11/3/06</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Linda Judge on 3/21/07.

The application has been amended as follows:

Cancel claims 73, 76, 77, 86, 87, 97, 100, 101, and 104-113.

Rewrite claims 72, 75, 78, 82, 96, 99, 103, 114, and 15 as follows:

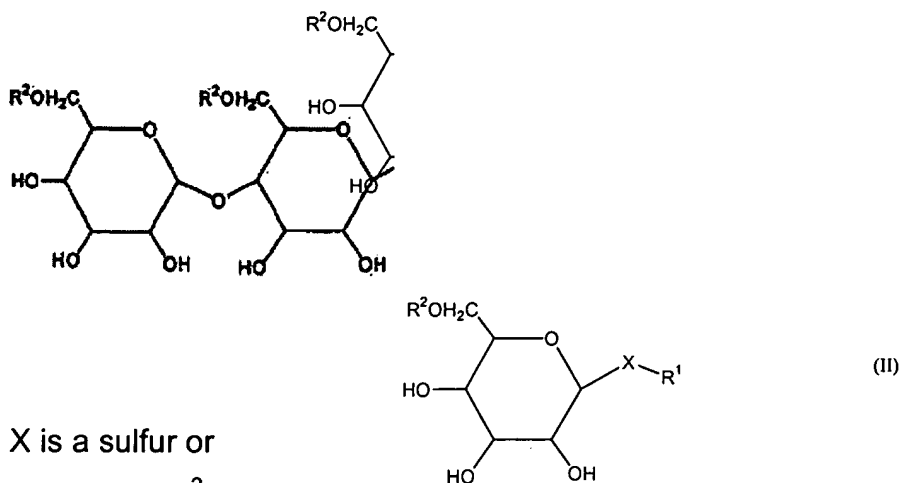
72. (Currently amended) A method for treating superficial cancer of the bladder derived from the bladder epithelium, comprising:

contacting the luminal surface of the bladder with a pretreatment composition comprising a transduction enhancing agent; and

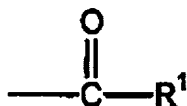
further contacting the luminal surface of the bladder with a composition comprising a replication competent oncolytic virus;

wherein cells of the bladder epithelium are transduced and the transduction enhancing agent has the following general formula (I):

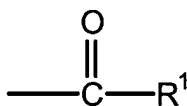
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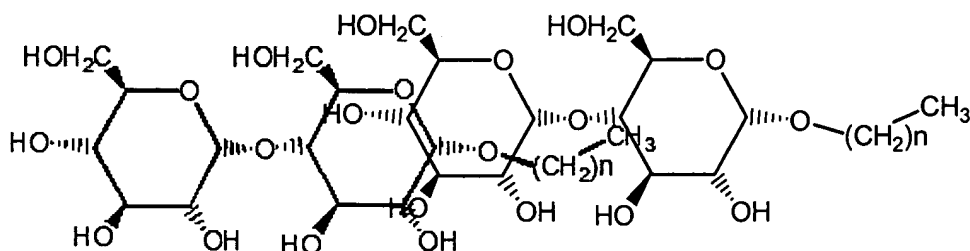
wherein X is a sulfur or oxygen atom, each R² is independently hydrogen or a moiety represented by:



and R¹ represents an alkyl or alkenyl group of 12 carbons.



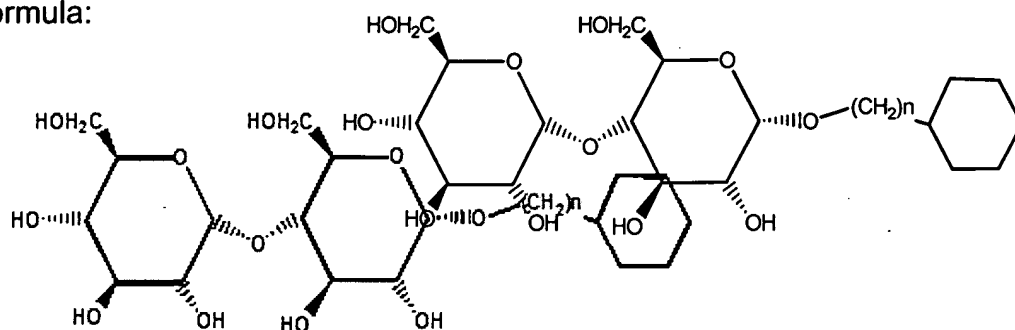
75. The method of Claim 72, wherein the transduction enhancing agent has the chemical formula:



wherein n is 11.

78. (Currently amended) The method of Claim 72, wherein the pretreatment composition comprises about 0.025 to about 0.4 % by weight of the transduction enhancing agent.

82. (Currently amended) The method of Claim 72, wherein the transduction enhancing agent has the chemical formula:



wherein n is 6.

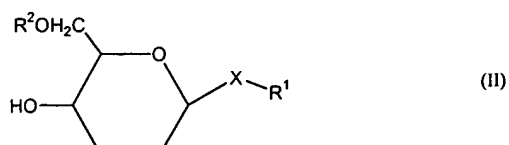
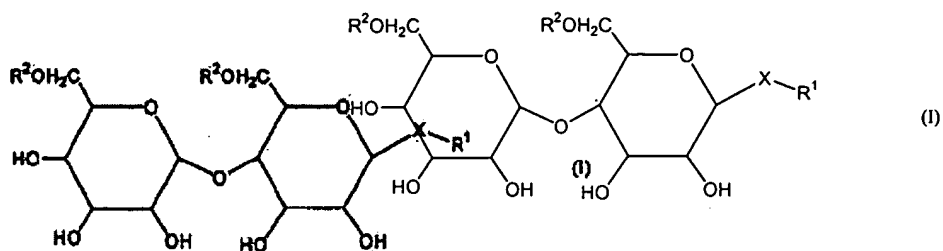
96. (Currently amended) A method for transducing bladder epithelium cells, comprising:

contacting the luminal surface of the bladder with a pretreatment composition comprising a transduction enhancing agent; and

subsequently contacting the luminal surface of the bladder with a composition comprising a replication competent adenovirus;

wherein the transduction enhancing agent has the following general formula (I):

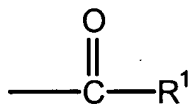
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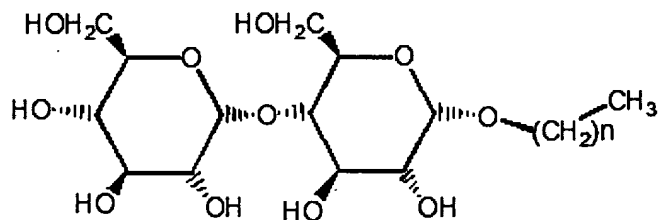
wherein X is an oxygen atom,
and each R² is independently
hydrogen or a moiety represented by:



wherein R¹ represents an alkyl or
alkenyl group of 12 carbons.

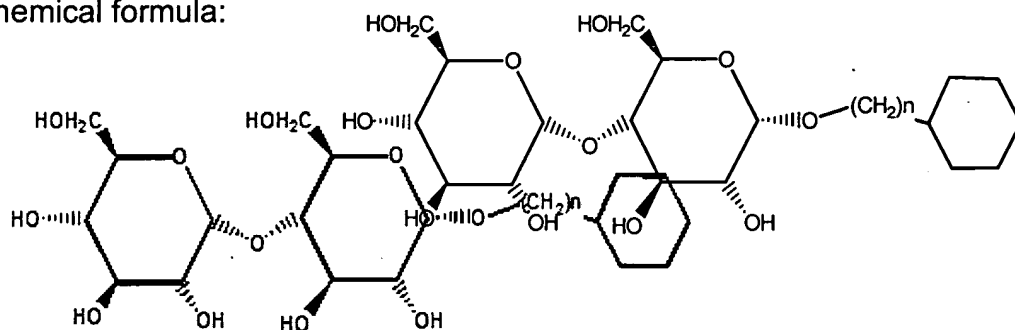


99. (Previously presented) The method of Claim 96, wherein the transduction enhancing agent has the chemical formula:



wherein n is 11.

103. (Currently amended) The method of Claim 96, wherein the transduction enhancing agent has the chemical formula:



wherein n is 6.

114. (Currently amended) The method of Claim 72, wherein the luminal surface of the bladder is contacted with a pretreatment composition comprising a transduction enhancing agent and a replication competent adenovirus at the same time.

115. (Currently amended) The method of Claim 72, wherein the luminal surface of the bladder is contacted with a pretreatment composition comprising a transduction enhancing agent prior to contact with a replication competent adenovirus.

Reasons For Allowance

The following is an examiner's statement of reasons for allowance: The obviousness rejections over the prior art of record are withdrawn in view of the Declaration of Dr. Frey, submitted 2/8/07, which demonstrates unexpected results for maltoside transduction agents with a 12-carbon hydrophobic group as the R1 moiety of Formula 1 of claim 72. Use of these agents yields transduction efficiencies greater than what would have been expected based on the prior art of record (e.g. Connor et al (2001)). These results also show that the maltoside transduction agents with a 12-

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carbon hydrophobic group as the R1 moiety perform significantly better than maltoside reagents with 10, 11, 13, or 14-carbon R1 groups. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

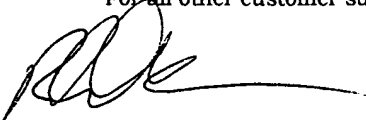
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Richard Schnizer, Ph.D.
Primary Examiner
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